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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,412	01/22/2001	Ruowen Ge	1781-0215P	7335

2292 7590 11/17/2004

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EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/766,412

Applicant(s)

GE ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-8,10,13-16,19,20,22,23 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) 10,15,16,20 and 23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,6-8,13,14,19,25-27 and 29 is/are allowed.
- 6) ☒ Claim(s) 22 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

ACKNOWLEDGMENT TO AMENDMENT, REMARKS, STATUS OF THE APPLICATION AND CLAIMS

1. The amendment and remarks filed 8/30/04 are acknowledged, entered and considered. In view of Applicant's request claims 1, 7, 19, 22, 27 and 28 have been amended, claims 3-5 and 9 have been canceled and claim 29 has been added. Claims 1, 2, 6-8, 10, 13-16, 19, 20, 22, 23 and 25-29 are now pending in the application of which claims 10, 15, 16, 20 and 23 are withdrawn as non-elected invention. Thus, the Office action is directed to the merits of claims 1, 2, 6-8, 13, 14, 19, 22 and 25-29 as *per* elected invention. Applicant is again advised to cancel non-elected invention. The objection to the specification and the rejections under 35 U.S.C. 112, second paragraph, 35 U.S.C. 102(b) over the prior art of record and 35 U.S.C. 112, first paragraph for claims 19 and 27 are withdrawn in view of Applicant's amendment and remarks filed 8/30/04. However, the rejection under 35 U.S.C. 112, first paragraph for claims 22 and 28 is maintained for the reasons of record.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. 112, ^{1st} PARAGRAPH

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the instant specification for the claimed methods of **preventing or treating a subject** for the conditions being claimed, such as primary tumor growth or metastasis by preventing or inhibiting tumor angiogenesis (claims 22 and 28).

Applicant's arguments filed 8/30/04 have been fully considered but they are unpersuasive. Applicant has argued that the specification describes the claimed invention and cites page 4, lines 12-15; page 6, lines 3-6; page 6, lines 6-10 (how to make); and page 7, line 19 through page 8, line 11 (how to use) is unpersuasive. Contrary to Applicant's arguments, the cited pages disclose how to identify, synthesize and protocols of how to use the claimed peptides. Further, as discussed in the previous Office action, the specification demonstrates *in vitro* tests of bovine aorta endothelial cell (BAE) proliferation assay for their ability to inhibit BAE cell proliferation, which provides a method for determining the anti-angiogenic activity of the peptides (See e.g., Examples 1-3 of the specification). Example 4 demonstrates that angio-3 can inhibit endothelial cell proliferation and retard tumor growth in mice. However, there is no *in vivo* showing for the effectiveness of the peptides as claimed nor there is a recognized model (identified as useful) being treated according to methods of **preventing or treating a subject** for the conditions being claimed.

With respect to Applicant's assertion that the enclosed reference of Ueda et al (Oral Oncol., Vol. 35, No. 6, pp. 554-560, 1999) shows the *in vivo* effectiveness of the peptides as claimed in a recognized model for methods of **preventing or treating a subject** for the conditions being claimed is unpersuasive. Contrary to Applicant's assertion, what Applicant has shown in the instant specification and the references cited to support Applicant's assertion is: infection + anti-angiogenic agents (e.g., portion of endostatin protein or TNP-470) = treatment **and not** infection + anti-angiogenic agents + prevention as asserted and claimed because for the **prevention** to occur, one must establish an infection + protocol (anti-angiogenic agents) with passage of time resulting in immune response = **prevention**. Further, Applicant's claims are directed to prevention, and there is no objective factual evidence in the specification or references enclosed or cited by Applicant to show that prevention has occurred since no adequate time was given to mimic the protocol administered in the animal models and allow evaluation of active immune response. Thus, one cannot administer at the point of infection and claim preventing or treating a subject for the conditions claimed without appropriate testing for the reasons discussed above.

ACTION IS FINAL

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CONCLUSION AND FUTURE CORRESPONDENCE

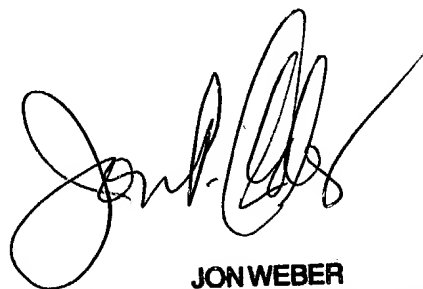
4. Claims 1, 2, 6-8, 13, 14, 19, 25-27 and 29 are allowed, claims 22 and 28 are rejected and claims 10, 15, 16, 20 and 23 are withdrawn as non-elected invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Jon Weber', with a large, stylized initial 'J' and a long horizontal stroke extending to the right.

JON WEBER
SUPERVISORY PATENT EXAMINER

AM Mohamed/AAM
November 8, 2004